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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,663	09/19/2001	David M. Roche	19629-7006	1221

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EXAMINER

LY, CHEYNE D

ART UNIT PAPER NUMBER

1631

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/955,663

Applicant(s)

ROCKE ET AL.

Examiner

Cheyne D Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' arguments filed June 16, 2004 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. The withdrawal of claims 13 and 14 has been acknowledged.
3. Claims 1-12, nucleic acid molecule, are examined on the merits.

OBJECTIONS

4. The disclosure is objected to because of the following informalities: Reference number 10 (page 15) wrongly cites "Rock, D.M."
5. Appropriate correction is required.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
8. The instant rejection has been necessitated by claim amendment.
9. Claim 1 recites the limitation "each model quantity" in the last line. There is insufficient antecedent basis for this limitation in the claim. The antecedent basis for said limitation is

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not clear because steps (a) to (g) do not recite any “model quantity” previous to the last line.

Claims 2-12 are rejected for being dependent from claim 1.

CLAIM REJECTIONS - 35 U.S.C. § 112, FIRST PARAGRAPH

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. NEW MATTER REJECTION.

12. The instant rejection has been necessitated by claim amendment.

13. The amendment to claim 1, last line, introduces new matter to the claims. Specifically, steps (b), (c), (e), and (g) are performed via estimating. The newly added limitation of “replaced by an estimate thereof” requires another step of estimating. The instant specification does not provide disclosure, as originally filed, for a method which requires the estimating to be perform with steps (b), (c), (e), and (g), and the estimating is repeated by the limitation of “replaced by an estimate thereof” in the last line of claim 1. Claims 2-12 are rejected for being dependent from claim 1.

CLAIM REJECTIONS - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1, 6-8, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rocke et al. (1995) taken with Bailey et al. (1987).

17. The instant rejection has been necessitated by claim amendment.

18. Rocke et al. discloses a method for estimating the precision measurements of biological samples (page 176, column 1, lines 25-30) using the estimated variance of equation 3.3 for low and high levels of the data measurements (page 179, column 1, §3.2; and Figure 4), as in instant claim 1, steps (a), (d), (f), and (g).

19. The method of Rocke et al. comprises a matrix (array) wherein data is derived from analyzing blanks (background parameter), additive error components (page 176, column 2, lines 16-18 and page 177, §2, lines 2-4), and standard deviation of data measurements (page 177, column 2, lines 6-8), as in instant claim 1, steps (b), (c), and (e).

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20. "For low levels, the average of n measurements will be approximately normally distributed with standard deviation" (page 179, column 1, §3.3). "As an example, suppose $O_e = 1$ part per billion (ppb) and $O_n = .1$. Then the standard deviation of blanks (negative control and background) is 1 ppb (page 177, column 2, lines 5-8), as in instant claims 6 and 7.

21. However, Roche et al. does not disclose the limitation of biological molecule is a nucleic acid.

22. The method of Roche et al. is directed to GC-MS analysis (page 177, column 1, lines 6-11).

23. Bailey et al. discloses a method for estimating exposure to alkylating carcinogens GC-MS determination of adducts in DNA (Abstract etc.), as in instant claims 8 and 10.

24. The method of Bailey et al. is an improvement for increasing the sensitivity of dosimetry by overcoming the presences of background levels (page 190, column 1, Conclusions §).

25. Roche et al. discloses a method for measuring near the detection limit (page 176, column 1, §1) as applied to environmental monitoring for low levels of toxic substances (page 178, column 2, §3).

26. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the improvement disclosed by Bailey et al. to utilize said improvement with the method of Roche et al. for environmental monitoring for low levels of toxic substances.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use a method of environmental monitoring for low levels of toxic substances as taught by Roche et al. and Bailey et al.

CONCLUSION

27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

28. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

29. This application contains claims 13 and 14 drawn to an invention nonelected without traverse, filed November 03, 2003. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

30. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

31. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free

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number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

32. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

34. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

C. Dune Ly

9/1/04

Andin H. Marschel 9/3/04
ANDIN H. MARSCHEL
PRIMARY EXAMINER